**Product eligibility under the COVAX Facility**

Products procured and/or supplied under the COVAX Facility must be quality assured to ensure positive impact on the population that receive them and to preserve the trust that has been placed in the Facility. Information about these products should be available to member states to enable them to make quick decisions on their importation and/or use and facilitate their continuous monitoring and oversite.

**To achieve this, the COVAX Facility should only consider:**

1. products listed by WHO Emergence Use Listing (EUL) or Prequalification (PQ) or,
2. under exceptional circumstances, products approved by a Stringent Regulatory Authority (SRA), hereunder to include Australia-TGA; EU-EMA; Canada-Health Canada; Switzerland-Swissmedic; UK-MHRA and USA-FDA.

**Background information**

a) Countries for reliance and streamlining assessment (abridged assessment)

The current definition of SRA has been adopted by the Expert Committee on Specifications for Pharmaceutical Preparations (ECSSP), whose scope is pharmaceuticals and not vaccines. The WHO Expert Committee on Biological Standardization (ECBS), under whose scope vaccines fall, has not defined SRA and has not used the term with respect to vaccines.

However, the PQ procedure for vaccines provides for facilitation of PQ through enhanced reliance on an authority that “exhibits a high level of performance of WHO’s six recommended regulatory functions and exercises full regulatory oversight of any given vaccine”. [WHO-TRS- 978 Annex 6, https://www.who.int/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf.] This is based on enhanced support to WHO during the PQ of pandemic H1N1 influenza vaccines and establishment of collaboration agreements in the evaluation and ongoing regulatory oversight of the vaccine of interest.

Until WHO has a list of National Regulators Authorities (NRAs) that have been assessed and designated as the **WHO Listed Authority (WLA) for vaccines, through the use of the Global Benchmarking Tool (GBT) and performance evaluation**, WHO-TRS- 978 Annex 6 provides for reliance on these NRAs that provided support to WHO during the PQ of pandemic H1N1 (2009) influenza vaccines.

As provided for in the TRS, the full list currently stands as follows:

1. Australia - TGA
2. Belgium - FAMHP
3. Canada - Health Canada
4. EU - EMA
5. France - ANSM
6. Germany - PEI
7. Italy - AIFA
8. Netherlands - MEB
9. Switzerland- Swissmedic
10. United Kingdom - MHRA
11. United States of America-USFDA

In the case of EU, the mandate for approval of new vaccines lies with EMA and therefore **only EMA is relevant from the EU authorities in the above list.** UK MHRA may need to be considered separately because of BREXIT. The other authorities outside EU should be considered separately, namely Australia-TGA; Health Canada; Switzerland-Swissmedic and USA-USFDA

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a) Functional NRAs

Oversight by a functional NRA is used as one of the conditions for manufacturers of vaccines to apply for prequalification (Eligibility to apply for PQ, TRS978, Annex 6, section 2). WHO does not process an application until the WHO NRA assessment is conducted and the outcome is satisfactory. Such a vaccine still undergoes **full assessment by WHO prequalification**. The functional NRA collaborates with PQ is exercising oversight of the prequalified vaccine, including production and lot release. The current list of functional NRAs is available on the following link [https://www.who.int/medicines/regulation/functional_nras_vaccine_producing/en/](https://www.who.int/medicines/regulation/functional_nras_vaccine_producing/en/). This is a list of countries that were assessed based on the vaccine tool before the GBT was developed. This will be replaced with NRAs at **Maturity level 3 (ML3) for vaccines following assessment based on the GBT**.

In conclusion, functional NRAs (ML3) for vaccines are used to determine eligibility for PQ vaccines assessment while WLAs for vaccines are used for abridged assessment for PQ of vaccines.